APR - 9 2001

Premarket Notification
TANDEM-CATH 10 Fr. Catheter System

ATTACHMENT 10

510(k) Summary

Date Prepared: April 5, 2000

Submitter: The Kendall Company, Div. Of Tyco Healthcare Group, LP

Contact: Regina Yeh
Senior Regulatory Affairs Specialist
Telephone: 508-261-8404, Fax: 508-261-8461

Device Trade Name: Kendall TANDEM-CATH 10 Fr. Catheter System

Device Common Name: Catheter, Intravascular, Short-term and Long-term

Classification Panel: Gastroenterology

Predicate Devices to Which Substantial Equivalence Is Claimed:

The Kendall TANDEM-CATH 10 Fr. Catheter System is substantially equivalent to the MedComp Bio-Flex CS Catheter and the Kendall Mahurkar® 13.5 Fr. Cuffed Dual Lumen Catheter.

Device Description:

The Kendall TANDEM-CATH 10 Fr. Catheter System consists of two 10 Fr. Single lumen catheters. Each catheter is 50 cm long, however, the implant length measured from the cuff to the distal tip differs in arterial and venous catheters. Each arterial catheter has an implant length 2.5 cm shorter than its paired venous catheter. The catheter lumens are distinguished by color-coded printing on the catheter shaft (red-arterial / blue-venous). The catheters will be offered with and without side holes. One configuration has 6 side holes oriented in a spiral pattern at the tip of both the arterial and venous catheters. The second configuration has no side holes on either the arterial or venous catheter. The TANDEM-CATH will be available in three different implant lengths. These variations are 19 cm / 22 cm (arterial / venous), 23 cm / 26 cm, and 28 cm / 31 cm.

The Kendall TANDEM-CATH 10 Fr. Catheter System is supplied in kits that include other accessory devices to be used during the catheter implant process. A Kendall TANDEM-CATH 10 Fr. Catheter repair kit will also be offered to replace damaged extensions and / or extension adapters.

Intended Use:

Kendall TANDEM-CATH Catheters are designed for hemodialysis, apheresis, and infusion. They are inserted percutaneously or by cutdown for adult patients. The preferred insertion site is the internal jugular vein.

Technological Characteristics:

The TANDEM-CATH 10 Fr. Catheter System is substantially equivalent to the Bio-Flex CS Catheter in regard to intended use, insertion technique, design, materials, physical specifications and performance characteristics. Like the Bio-Flex CS Catheter, the Tandem-Cath uses separate catheters for arterial and venous circulation and is inserted via a reverse tunneling method. The physical design are very similar in that both are made of polyurethane, both are 10 Fr., both catheters are available in the same three different arterial / venous implant depths, and both utilize catheter extension adapters to provide external access to the catheters following insertion using the reverse tunneling procedure.

Performance Data:

The TANDEM-CATH and Bio-Flex CS Catheters perform very similarly in regard to dynamic flow, static flow and stiffness. The TANDEM-CATH also conforms to requirements of International Standard ISO 10555-1 in regard to tensile strength, burst pressure, leakage and flexural fatigue.

Regina Yeh
Senior Regulatory Affairs Specialist
The Kendall Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Ms. Regina S. Yeh
Sr. Regulatory Affairs Specialist
The Kendall Company
15 Hampshire Street
MANSFIELD MA 02048

Re: K002902
Kendall Tandem-Cath 10 Fr. Catheter System
Dated: January 8, 2001
Received: January 9, 2001
Regulatory Class: III
21 CFR §876.5540/Procode: 78 MSD

Dear Ms. Yeh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for

Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002902

Premarket Notification
TANDEM-CATH 10 Fr. Catheter System

Indications for Use Statement

Devise Name: Kendall TANDEM-CATH 10 Fr. Catheter System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____(Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002902